DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 10, 2015

HS HOSPITAL SERVICE SPA
% Maurizio Pantaleoni
ISEMED srl
Via Altobelli Bonetti 3/A, Imola
40026 Bologna
Italy

Re: K150112
Trade/Device Name: HS AMICA devices family
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 14, 2015
Received: January 14, 2015

Dear Pantaleoni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part

807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150112

Device Name

HS AMICA DEVICES FAMILY

Indications for Use *(Describe)*

Coagulation (thermoablation) of soft tissue. Not for use in cardiac procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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HS Hospital Service SpA. HS AMICA devices family

V. 510(k) Summary

HS AMICA devices family

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

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Summary Preparation Date: July 28, 2015

2. Device

Device Name: HS AMICA devices family

Classification name: Electrosurgical cutting and coagulation device and accessories

Product Code: GEI

Regulation number: 878.4400

Class: II

3. Predicate Device

HS AMICA devices family is substantially equivalent to the following devices:

HS Hospital Service SpA. HS AMICA devices family

Applicant	*Device name*	*510(k) Number*
H.S. HOSPITAL SERVICE S.P.A.	HS AMICA	K083157
VALLEYLAB	COOL-TIP RF SYSTEM	K053290

The HS AMICA devices family has to be used for the coagulation (thermoablation) of soft tissue; not for use in cardiac procedures.

The thermoablation is obtained by microwave- and radiofrequency-based technologies. Especially, the HS AMICA devices family is equivalent to the predicate device K083157 concerning the microwave performance and to K053290 with regard to the radiofrequency thermoablation.

4. Device Description

HS AMICA devices family is an integrated system for thermoablation of tissues through controlled emission of non-ionizing electromagnetic radiations in the microwave and radiofrequency ranges.
Especially the HS AMICA family consists of 3 devices and relative accessories emitting:

1. Only microwaves (MW) or
2. Only radiofrequency waves (RF) or
3. Either microwaves or radiofrequency waves (not simultaneously)

The three devices emit the specific wavelength through their applicators (probes) that are inserted into the human body and deliver electromagnetic energy through their emitting tip, causing the thermoablation. Such functions are identical to the predicate devices and especially to the HS AMICA (K083157) concerning the microwave ablation and to the Cool-tip system (K053290) concerning the radiofrequency ablation.

Briefly, the HS AMICA devices family consists of two main components: **1)** the generator; **2)** the applicator (probe).

The generator of the electromagnetic energy is available in the following variants, depending on the specific electromagnetic emission:

1. AMICA GEN AGN-H. This variant is characterized by both the MW and RF modules that must be selected by the physician. When the MW function is selected, the RF emission is disabled and viceversa and thus the modules operate in mutually exclusive fashion
2. AMICA GEN AGN. This variant has only the MW module.
3. AMICA GEN AGN-R This variant has only the RF module.

In all cases, the AMICA GEN is provided with an electronic control unit ***(EC)***, for data exchange with the patient applied parts, the interpretation of user's commands through front panel controls or external peripherals (such as the footswitch for remote energy start/stop), the continuous update of the machine indicators, and the control of the energy generation modules ***MW*** and/or ***RF***.

In light of the overall set of input values and upon proper verification of possible alerts or alarms, ***EC*** allows:

- enabling/disabling of MW or RF energy delivery (for the AMICA GEN AGN-H) through an appropriate signal for switching the amplifier A or A_{RF} on/off
- fixing the MW/RF output level by adjusting the gain control voltage
- generating messages and feedback signals through the front end indicators featured by AMICA-GEN (all the variants)

The applicator (probe) is disposable and consists of the following variants, to be used for the MW or RF thermoablation:

1. AMICA PROBE. This variant is a microwave coaxial antenna of asymmetric dipole type allowing the emission of the MW energy
2. RF AMICA-PROBE. This variant is used for radiofrequency energy delivery through monopolar interstitial electrode.

HS AMICA devices family consists of non-sterile reusable electronic parts, and sterile disposable applied parts, identically to the predicate device HS AMICA (K083157).

The disposable components are supplied in sterile conditions (possibly kit with sterile disposable accessories) and they can not be re-sterilized.

The sterile components are:

1. Single use kit containing AMICA PROBE with its accessories
2. Single use kit containing RF AMICA PROBE with its accessories :

The sterilization method used for all the sterile components is Ethylene Oxide.

The method is exactly the same used and validated for the predicate device cleared in K083157.

The part of the HS AMICA devices family coming in contact with patient are : AMICA-PROBE and RF AMICA-PROBE. According to Table 1 of *Blue Book Memo, G95-1 "Required biocompatibility Training and toxicology Profiles for Evaluation of Medical Devices"*, the contact between the devices and the patient is limited under 24 hours, usually less than 30 minutes.

Material used to manufacture the parts of AMICA-PROBE and RF AMICA-PROBE coming in contact with patient are:

- For AMICA-PROBE:
  - Polytetrafluoroethylene (PTFE)

  Such material is exactly the same material used in the previously cleared device HS AMICA (K083157) and proved to be biocompatible.

- For RF AMICA-PROBE:
  - Stainless steel (AISI 304) coated with Polyethylene terephthalate (PET)

  Such material has been proved to be biocompatible according to ISO 10993.

5. Indications for use

Identically to the predicate device HS AMICA (K083157), the indication for use of HS AMICA devices family is: "Coagulation (thermoablation) of soft tissue. Not for use in cardiac procedures"

The Indications for use of the predicate device K053290 is not identical to the subject device just because it includes either the ablation of tissue (identically to the subject device) or the laparoscopic coagulation (which is not provided with the subject device). Therefore the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the subject device relative to the predicate.

6. Comparison of technological characteristics with the predicate devices.

The thermoablation is the technological principle for both the subject and the predicate devices. It consists of the delivery of microwave or radiofrequency energy to the target tissue, by means of dedicated applicators (probes). The subject device consists of three variants allowing the emission of both the microwave and the radiofrequency (not simultaneously). Concerning the microwave thermoablation the subject device may be found equivalent to the predicate HS AMICA (K083157), while for the radiofrequency thermoablation the subject device may be found equivalent to the predicate Cool-tip system (K053290).

At high level the subject and the predicate devices are based on the following same technological elements:

- Design structure: both the subject and the predicate devices consist of a generator provided with a cooling system and an applicator (coaxial microwave applicator and radiofrequency applicator) connected the generator
- Power output: the subject device has a power output up to 200 W identically to the predicate K053290
- Cooling system both the subject and the predicate device (K083157) provide an automated cooling system
- Time of treatment: both the subject and the predicate device K053290 allow up to 30 minutes of treatment
- Needle temperature: both the HS AMICA devices family and the predicate devices K083157 and K053290 allow the detection of the needle temperature within equivalent range of temperature.
- Microwave emission frequency: the subject as well as the predicate device K083157 emit at 2450 MHz
- Microwave emission management: the management of the microwave power is manually regulated for both the subject and the predicate device K083157
- Radiofrequency emission frequency: the emission frequency of the subject device (450 KHz) is equivalent to the emission frequency of the predicate device K053290 (480 KHz ±10%)
- Radiofrequency emission management: both the subject and the predicate device K053290 allow manual and automatic management of the radiofrequency power delivery.
- Operative impedance range: both the subject and the predicate device K053290 adopts the same operative emission range to control power delivery
- Microwave applicator: both the subject and the predicate device (K083157) have an applicator equipped with stainlees steel needles.
- Radiofrequency applicator tipologies: both the subject and the predicate device K053290 use single and cluster applicators.
- Condition of use of applicators: both the subject and the predicate devices K053290 and K083157 use sterile and disposable applicators.

The following technological differences exsist between the subject and the predicate devices:

- Radiofrequency emission management-*algorithms:* specific algorithms are used by the subject and the predicate device K053290 to control the maximum power deliverable at the target site. Such control is based on the detection and control of the impedance of the tissue, in both the devices. However, the subject device has an additional control: a specific algorithms allows to control the operative temperature which is selected by the physician by decreasing the RF power delivery for not exceeding the selected temperature. Such feature does not raise new safety nor effectiveness issues and better yet it satisfies higher safety standards.
- Radiofrequency applicator: both the subject and the predicate device K053290 use applicator stainless steel needles. However the dimensional characteristics of the needles of the subject device are slightly different relative to the predicate device.
  However in no way such differences affect the effectiveness nor the safety of the subject device as demonstrated by a specific performance test (see below).

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination

- Electrical safety

The subject device was tested for the electrical safety demonstrating that it complies with AAMI ANSI ES60601-1:2005 (19-5) and IEC 60601-2-2 (6-228).

- Electromagnetic compatibilities:

The subject device was tested according to AAMI ANSI IEC 60601-1-2 (19-2). The results demonstrate the compliance with the standard.

- Software verification and validation

The HS AMICA medical devices family has been developed and validated according to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices requirements FDA – May 2005 and according to IEC 62304:2006 (13-8).

- Biocompatibility
  The biocompatibility evaluation for the subject device was conducted in accordance with Blue Book Memo, G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' and the International standard ISO 10993-1 (2-156).

- Performance test-bench

Two specific tests were conducted to verify the performance of the subject device compared to the predicate devices K053290 (concerning the radiofrequency ablation) and K083157 (concerning the microwave ablation). The effectiveness of the performance was evaluated through the measurement of the size of the obtained ablation (depth, width and length) on different ex-vivo tissues (muscle, liver, lung and kidney) when considering minimum, maximum and default power setting and all the available gauges and needles.

The results demonstrate that the ablations obtained with HS AMICA have equivalent dimensions compared to the predicate devices K053290 (RF ablation) and K083157 (MW ablation) proving that the performance of the HS AMICA device is at least as good as the performance of the predicate devices.

8. Conclusions

The performance data including in particular the electrical safety, EMC, software verification and validation support the safety of the HS AMICA devices family and demonstrate that the subject device performs as intended in the specific use conditions. Also, the considerations and bench tests discussed above underline the equivalence of the subject device to the predicate device K083157 with regards to the microwave ablation and to the predicate device K053290 with particular regard to the radiofrequency-based thermoablation.

Therefore, on the basis of evidence discussed above, the HS AMICA devices family may be found substantially equivalent to the predicate devices (K083157 and K053290).